

REMARKS/ARGUMENTS

Claims 1-49 were pending in the application. Claims 1-25 and 30-47 were withdrawn from consideration as being directed to non-elected subject matter. Applicants reserve the right to prosecute these claims in a subsequent continuing/divisional application. Claims 26-29 and 48-49 have been examined. Claims 26-29 and 48-49 currently stand rejected. Claim 26-29 and 49 have been canceled. Claim 48 has been amended herewith to further point out and distinguish the present invention from the references. Claims 50-57 are newly added. Support for the amended and added claims can be found throughout the Application as originally filed on April 12, 2004, and published as US 2005-0228413 A1 (hereinafter "Application") including pages 1-2, 5, 7, 13 and Figs. 4 and 19-20, for example. Reexamination and reconsideration of the claims are respectfully requested and appreciated.

Claim Rejections - 35 USC §103

Claims 26-29 are rejected under 35 USC §103(a) as allegedly unpatentable over US 6,113,611 in the name of Allen et al. (hereinafter "Allen") in view of US 2003/0093118 (now US 6,960,221) in the name of Ho et al. (hereinafter "Ho"). See Office Action pages 2-3. Claims 26-29 have been canceled making this rejection moot.

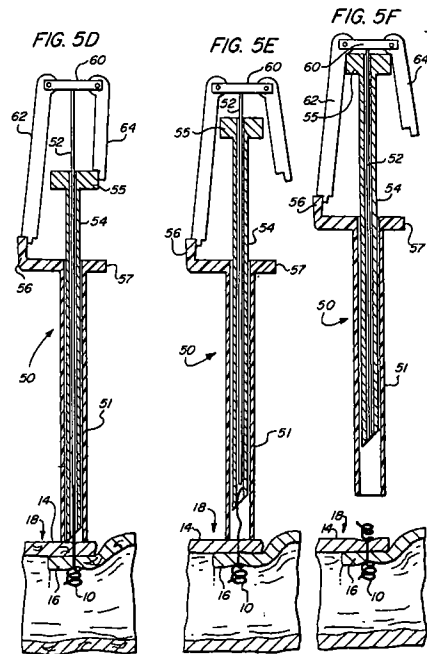
Claims 48-49 are rejected under 35 USC §103(a) as allegedly unpatentable over Allen in view of US 5,520,700 in the name of Beyar et al. (hereinafter "Beyar"). See Office Action pages 3-4. Applicants respectfully traverse the rejection of claim 48.

The Supreme Court articulated the test for obviousness in *Graham v. John Deere Co.* (hereinafter "*Graham*"). 383 U.S. 1 (1966). The Graham factors for determining obviousness are: (1) analysis of the scope and content of the prior art; (2) a determination of the level of ordinary skill in the art; (3) analysis of the difference between the prior art and the claimed invention; and (4) consideration of the extent of any objective indicia of non-obviousness, such as surprisingly effective results. Recently, the Supreme Court reaffirmed the *Graham* standard for obviousness in *KSR Intl Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1391 (2007). The Court noted that any analysis supporting a rejection for obviousness must be made explicit, and that it is "important to identify a reason that would have prompted a person of

ordinary skill in the relevant field to combine the [prior art] elements in the manner claimed". *Id.* at 1741.

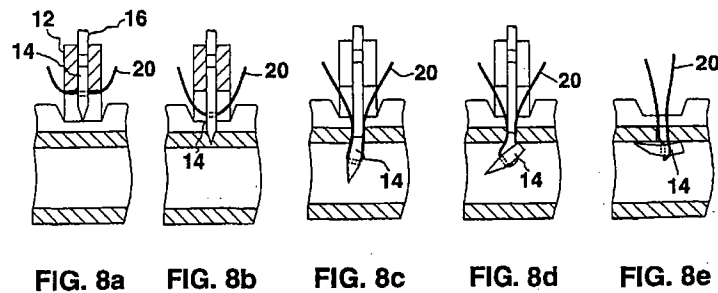
Claim 48, as amended, recites. a method for anchoring a tissue to a luminal structure by positioning an apparatus next to a wall of a luminal structure and manually advancing an assembly member, including *a hollow cylindrical central member*, from the apparatus through a tissue penetration. A first anchor is deployed from the hollow central member such that the first anchor-engages the tissue on a distal side. A second anchor is deployed from the hollow central member such that the second anchor engages the tissue on a proximal side. *The radius of the central member expands to provide a lumen through the tissue.* The expanded central member and deployed anchors hold the assembly in place. (*emphasis added*).

Allen teaches a *solid wire* fastener that is elastically deformed. Figures 5D-5F below show that to apply the fastener 10, a straight tube or needle 54 of the deployment instrument 50 is used to hold and deflect the fastener from its final coiled shape into a straight configuration. After the fastener is deployed, it gradually assumes its original coil shape to trap and compress tissue layers 14, 16 (see also abstract, column 3, lines 46-57 and Figs. 1C and 4). Thus, the fastener is forced into a straight line after forming and is able to "remember" its former shape and return to it when no longer constrained within a straight tube.

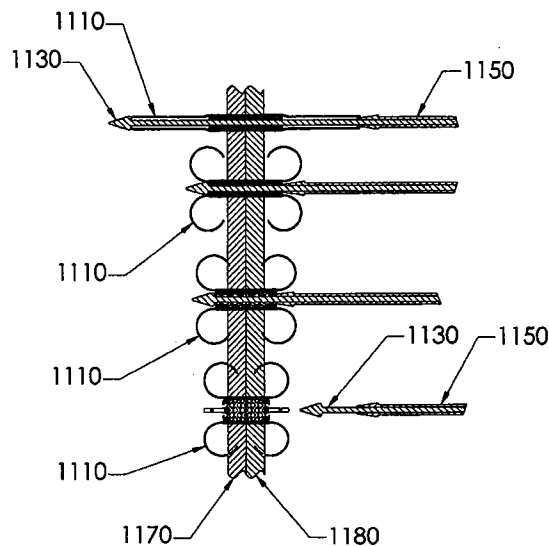


Allen does not teach a method of anchoring tissue to a luminal structure using, in part, a *hollow cylindrical central member that radially expands to provide a lumen through the tissue* to create an anastomosis. Allen's device does *not* create an anastomosis.

Beyar teaches a T-tag stapling device to anchor a suture to bone. As per the deployment sequence shown below in Figs. 8a through 8e, the device appears to change orientation after insertion but it does *not* have a *hollow cylindrical central member that expands the radius of the central member to provide a lumen through the tissue* to create an anastomosis, for example. Beyar's device does *not* create an anastomosis or any other fluid communication between tissues.



This lies in stark contrast to the present invention which discloses advancing an assembly member, including a *hollow cylindrical central member*, from the apparatus through a tissue penetration. Deploying anchors and expanding the *radius of the central member to provides a lumen through the tissue* to create an anastomosis. The sequence of delivering an anchor is shown in four steps beginning at the top of Fig. 19. The final step shows the deployed anchor and the central member in a radially expanded configuration.



The anchors deploy and the radius of the *hollow central member* expands while holding the tissue 1170, 1180 in place relative to a region of the luminal structure. As the expander 1130 retracts, it may force the anchor 1110 to expand. This expansion may result in an anchor having a greater diameter at its distal end. Increased compression force on the pusher

1150 may load the anchor 1110 in compression. The compression loading of the anchor 1110 may yield the material and cause plastic deformation (see page 7, paragraphs 0089-0090).

Accordingly, Beyar does not make up for the shortcomings of Allen. Significant and unobvious differences exist between the scope and content of Allen and the invention recited in independent claim 48, as amended, such that this claim and the claims that depend from it are allowable over Allen in view of Beyar per *Graham*.

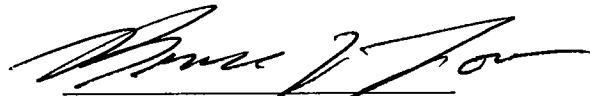
Therefore, significant and unobvious differences exist between the scope and content of Allen and the invention recited in independent claim 48, as amended, such that this claim and the claims that depend from it are allowable over Allen in view of Ho per *Graham*.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



Brad J. Loos
Reg. No. 51,968

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 415-576-0300
Attachments
BJL:llm
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